ADVOCATE™

TD-4223 A/B

BLOOD GLUCOSE

MONITORING SYSTEM

OWNER'S MANUAL

331-4224200-001
Version 1.0 November 2006

Dear Advocate™ TD-4223 A/B System Owner:

You have chosen one of the best blood glucose monitoring systems. This manual contains important information you must know about the system. Please read it thoroughly and carefully.

The greatest feature of this system is its **speaking function** (with a talking symbol on the meter), which is an acoustic aid for users especially with visual disability. Please note that this function is optional. If the meter does not have , it will not provide speaking function.

Another unique feature is its **internal established code.** Not only does it simplify the glucose test, it also provides you and your doctor with more precise and accurate test results.

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or the testing of newborns.

PLEASE NOTE

Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional. These recommendations apply to all blood glucose monitoring systems and are supported by the Diabetes Educator Section of the Canadian Diabetes Association.

IMPORTANT SAFETY INSTRUCTIONS
READ THIS BEFORE USING

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.

2. Use the device only for the intended use described in this manual.

3. Do not use strips and control solutions which are not supplied by the manufacturer.

4. Do not use the device if it is not working properly, or if it has suffered any damage.

5. Do not use the device near a mobile phone or microwave oven, or it may cause inaccurate results.

KEEP THESE INSTRUCTIONS

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IMPORTANT INFORMATION

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

- Test results below 60 mg/dL* [1](3.3 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL* [2](13.3mmol/L) mean high blood glucose (hyperglycemia). If you get results below 60 mg/dL or above 240 mg/dL, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 40 mg/dL, follow the treatment advice of your healthcare professional.

- Apply only capillary whole blood sample to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate results.

- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.

- A red blood cell count (hematocrit) that is very high (above 60%) or very low (below 20%) can cause false results.

- The following **WILL NOT** affect results:
  Elevated blood triglyceride, reducing substances such as uric acid and ascorbic acid when occurring in expected blood concentration, or acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentrations.

- This system may be used at altitudes up to 10,742 feet (3,275 m) without an effect on test results.

*1. Kahn, R., and Weir, G,: Joslin's Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.
*2 Krall, L.P. and Beaser, R.S. Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

ABOUT ALTERNATIVE SITE TESTING (AST)

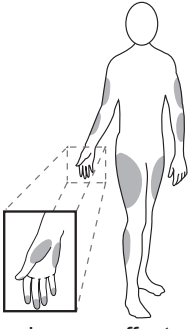
Important: There are limitations for doing AST. Please consult your healthcare professional before you do AST.

What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. This system provides you to test on the palm, the forearm, the upper arm, the calf, or the thigh with the equivalent results to fingertip testing.

What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings were not so condensed, you will not feel as much pain as at the fingertip.



When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other events, **take blood samples from your finger only.**

We strongly recommend you do AST **ONLY** in the fol - lowing intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your blood glucose is low.
- If you are awareness of being hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- If you are pregnant.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concen - tration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

If you would like to obtain blood from sites other than the finger, replace the lancet device cap with the clear cap. The clear cap for AST is an optional accessory, please contact your local customer service.

- **NOTE: We suggest that before getting a drop of blood rub the pucture site about 20 seconds before penetration.**

◉ INTRODUCTION OF THE SYSTEM

■ Intended Use

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

■ Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

■ Contents of the System

The system should be used with three main products: the blood glucose meter, test strips, and a control solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only the Advocate™ test strips and Advocate™ control solution with your Advocate™ TD-4223 A/B Monitor.

Your system includes:

1. A Meter
2. Owner's manual
3. Sporty carrying case
4. Quick reference guide
5. Warranty Card

PLEASE NOTE

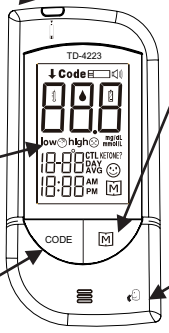
Check your system to be sure that it is unopened prior to use and that it contains all parts listed above. If either of these conditions occurred, please return your system to the place of purchase.

■ Appearance and Key Function of the Meter

TEST SLOT
Is where you insert the test strip. The meter will turn on automatically after insertion.

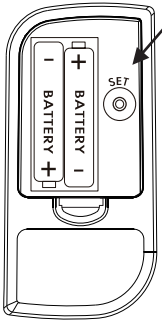
LCD DISPLAY
Guides you though the test using symbols and simple messages.

CODE BUTTOM
Located in front of the meter, is for code selection.

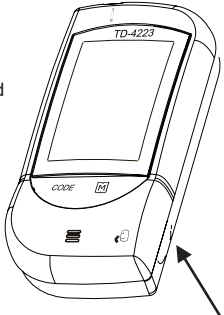


MAIN BUTTOM
Located in front of the meter with "M" on it, is used to turn on the meter, enter the memory mode and control steps of setting.

TALKING SYMBOL
Indicate that the meter contains speaking function.



SET BUTTON
(in the back) located in the battery compartmen, is used to set up the meter.



DATA PORT
Located at the side, is for cable connection.

■ Meter Display Segments

TEST STRIP SYMBOL
Appears when the meter is turned on.

BLOOD DROP SYMBOL
Flashes when it is ready to apply the sample.

CODE
Appears with the code number currently in use.

TEMPERATURE SYMBOL
Appears when ambient temperature is outside operating temperature.

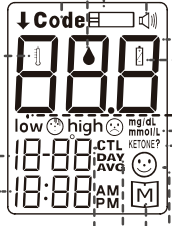
TIME

DATE

CTL SYMBOL
Appears when doing a control test and indicates that the result will not be stored in the memory.

DAY AVERAGE
Indicates that the displayed test result is an average.

MEMORY SYMBOL
Appears when you review the memory.



VOICE SYMBOL
Indicates speaking function is on/off.

TEST RESULT AREA
Displays glucose results. A decimal point appears when the measurement unit is mmol/L.

LOW BATTERY SYMBOL
Appears when the battery power is low.

FACE SYMBOL

LOW/HIGH SYMBOL
Both are result indicators. They appear together with the test result which exceeds the reference range.

MEASUREMENT UNIT
Appears with the test result either in mmol/L or in mg/dL.

KETONE WARNING
Appears when the test result is equal or higher than 240mg/dL (13.3mmol/L).

SMILE SYMBOL
Appears when the test result is within reference range.

■ Speaking Function

When a talking symbol is on the meter, it means that the meter provides speaking function. It “speaks” step by step and leads you through a blood glucose test. The following table tells you when and what the meter “speaks”. Those messages can also be found in the end section of this manual “SUMMARY OF OPERATION”.

WHEN does the meter speak?	**WHAT does the meter speak?**
When meter is turned on	A welcome music plays. Thank you for using this product. Please relax during measurement .
When room temperature is detected.	The room temperature is (number) degree Celsius/ Fahrenheit.
When room temperature is outside operating range.	Room temperature out of range, unable to measure.
After inserting test strip and completing code selection.	The code number is (number)
When the meter is ready to test. (“ ▲” symbol appears on display)	Please apply blood into the strip.
When the test is completed. (The result appears on display)	The blood glucose is (number) Milligram Per Deciliter/ Millimole Per Liter.
When the test result is outside measurement range, which is 20-600 mg/dL.	The blood glucose out of range, unable to measure.
When turn off the meter.	An ending music plays.

■ Appearance of the Test Strip

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:

Contact Bars
Insert this end of the test strip into the meter.
Push it in firmly until it will go no further.

Test Strip Handle
Hold this part to insert the test strip into the slot.

Confirmation Window
This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

Absorbent Hole
Apply a drop of blood here,
The blood will be sucked in automatically.

Please see pages 29-35, “Testing Your Blood”, for complete instructions.

PREPARATION BEFORE USE

Battery Replacement

Your meter comes with two 1.5V AAA size alkaline batteries.

The meter will alert you when the power is getting low by displaying two different messages:

1. The symbol appears together with other display messages: the meter is functional and the result remains accurate, but it is time to change the batteries.

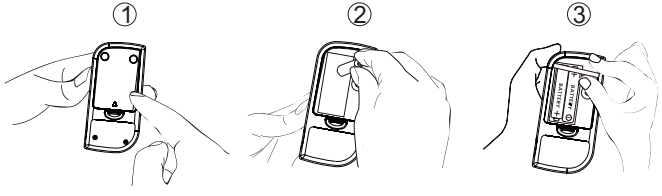
2. The symbol appears with the E-b symbol and “low”: the batteries can not provide enough power to do a test. You must change the batteries immediately.

PLEASE NOTE

- Replacing the batteries does not affect the meter’s memory (previous test results stored in memory). However, the time and date settings may need to be updated.
- Batteries might leak chemicals if not used for a long time. Remove the battery if you are not going to use the device for an extended period (i.e., months or more)

To replace the batteries, make sure that the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries. Make sure that the positive “+” side is facing up.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep".



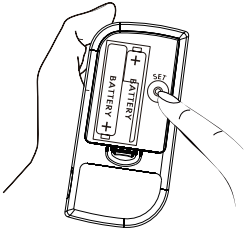
WARNING

As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.

■ Setting the Meter and Deleting the Memory

Your meter comes with the time, date, unit of measurement and unit of temperature preset. However if you replace the batteries, you may need to reset the setting of the meter.

Start with the meter off. Then press the Set button located in the battery compartment. The meter is now in the setting mode. You can start setting up the meter.



STEP 1. Set the Year
The year will appear first, with the year setting flashing. Press and release the M button to advance one year. To move faster, keep pressing the M button until the desired number appears. With the correct year on the display, press the Set button and then the month segment flashes.

STEP 2. Set the Month

Press and release the Ⓜ button until the correct month appears. To move faster, hold the Ⓜ button down. With the correct month on the display, press the Set button and then the day segment flashes.

STEP 3. Set the Day

Press and release the Ⓜ button until the correct day appears. To move faster, hold the Ⓜ button down. With the correct day on the display, press the Set button and then the hour segment flashes.

STEP 4. Set the Hour

Press and release the Ⓜ button to advance one hour. To move faster, hold the Ⓜ button down. With the correct hour on the display, press the Set button and then the minute segment flashes.

STEP 5. Set the Minutes

Press and release the M button to advance one minute. To move faster, hold the M button down. With the correct minute on the display, press the Set button and then the current unit of measurement starts flashing.

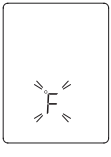
STEP 6. Select mg/dL or mmol/L

Press and release the M button to select the unit of measurement you want to use. Press the Set button and then the current unit of temperature flashes.

The milligram per deciliter (mg/dL) is the standard unit in the United States. The mmol/L is the standard unit in Canada.

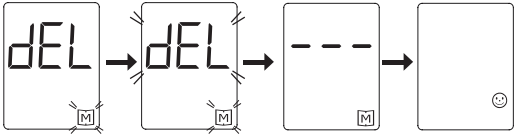
STEP 7. Select °C or °F

Press and release the M button to select the unit of temperature you want to use. Press the Set button and the meter will display “dEL” with flashing “ M ” symbol.



STEP 8. Delete the Memory

When “dEL” and blinking “ M ” symbol is displayed, if you do not want to delete memory, press the Set button again to skip this step. If you would like to delete **ALL** memory, press M button, both “dEL” and “ M ” will flash. **Press the M button again to delete ALL memory.** “---” and “ M ” are displayed on the meter, following “ ☺ ” means that all data stored are deleted. The memory of this meter is empty now.



If your meter has a talking symbol on it, please press the Set button to proceed to the next step.

If not, you have completed the setting mode. Press the Set button to turn off the meter. “OFF” is displayed before shut down.

PLEASE NOTE

- The time, date, unit of measurement and unit of temperature can **ONLY be changed** in the setting mode. Therefore, when you perform a glucose testing, those parameters are not possible to be changed.
- Your meter displays 7, 14, 21, 28, 60 and 90 day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7, 14, 21, 28, 60 and 90-days preceding the current date and time settings. When the date and time are changed, the 7, 14, 21, 28, 60 and 90-days averages may change.
- While the meter is in the setting mode, if no button is pressed for 3 minutes, the meter will turn off automatically.

STEP 9. Select Speaking Function

The meter displays “VOL”, “ ” and flashing number. Press the M button to select speaking volume from 0 to 7. Then press the Set button to proceed to the next step.

Number 0 indicates that the speaking function is turned off, where “ ” does not display on LCD during testing. Number 1 to 7 indicates speaking volume from low to high, where “ ” displays on LCD during testing.

STEP 10. Select Languages

L1/L2 and “ ” display on LCD. Press the M button to select. Two languages can be selected.

The setting mode is all completed. Press the Set button to turn off the meter. “OFF” is displayed before shut down.

Congratulations! You have finished your meter setting.

BEFORE TESTING

Checking the Display

Each time you insert a test strip, the meter displays ”CH” and ” ”. This tells you that the system is performing several self-checks.

Calibration

When using the system for the first time, or before using a new vial of test strips, you will need calibration, which can be easily done by selecting the correct code from the meter. It is important to make sure that the LCD displayed code is the same as the code on the test strip vial before you proceed. **Only test blood glucose when the codes are identical, so the test results will be accurate.**

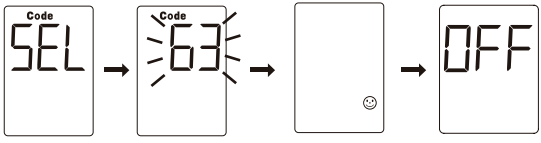
Calibration can be approached by pressing the CODE button when: A) the meter is off, or B) the meter has a test strip inserted. Please calibrate the meter according to the following steps.

CAUTION

If the code number displayed on the meter does not match the number printed on the vial, test results may be inaccurate.

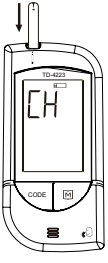
A) Calibrate when the meter is off, directly press the CODE button.

Press the Code Button. With “Code” and “SEL” appear first, the flashing code number shows. Press the CODE button to advance one number until the correct code appears. Press the button [M] to set the code. The symbol “☺” and “ OFF ” appear, which indicate that calibration is complet. The meter will turn off automatically.



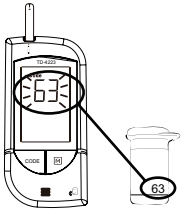
B) Calibrate when the meter has a test strip inserted.

STEP 1. Insert the Test Strip
Start with the meter off. Insert a test strip into the test slot. LCD displays “CH” and " ▭ " first, the ambient temperature next, and finally a flashing code number.



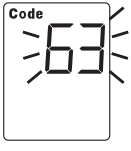
STEP 2. Match the Code Number

Compare the flashing number with the code number on the test strip vial. If two numbers match, press the M button or wait 5 seconds to fix the code. Then date, time and the flashing " 🩸 " appear on the screen, indicating that you can directly begin testing. If they do not match, follow STEP 3 .



STEP 3. Select a Correct Code

While the code number is still flashing, press the CODE button to advance one number. When the correct code appears, press the M button or wait 5 seconds to fix the code. Then date, time and the flashing " 🩸 " appear on the screen. You can begin testing.



If you would like to turn off the meter, remove the test strip and then "OFF" is displayed before shut down or wait 3 minutes for automatically shutting down.

■ Checking with Advocate™ Control Solutions

Advocate™ control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, it is able to check that

the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

How often the control solution test should be performed?

- When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- To routinely check the meter and test strips, perform a single test for each level of control solution supplied at least once a week.

When the control solution test should be performed?

- When you first get your Glucose Meter.
- When you begin using a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- When your test strips are exposed to extreme environmental conditions.

  (See Storage section of this manual).
- When you want to practice running the test.
- If you drop the meter.

■ Important Control Solution Information

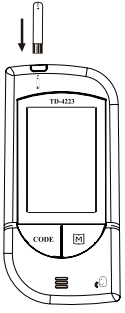
- Use only Advocate™ control solutions.
- Check the expiration date on the control solution vial. Do not use if expired.
- Control solution, meter, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.
- Store the control solution tightly closed at temperatures below 30°C (86°F). Do not refrigerate.

PLEASE NOTE

The control solution range printed on the test strip vial is for Advocate™ control solution only. It is used to test meter and test strip performance. It is not recommended range for your blood glucose

■ Doing a Control Solution Test

STEP 1. Insert the Test Strip
Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the following in sequence:
→ "CH" and "▭"
→ ambient temperature
→ flashing code number
→ date, time, flashing "💧" and the code number



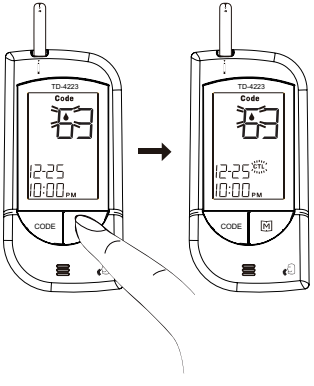
Be sure the code number on the display is the same as the code number on the test strip vial. If the code numbers do not match, please see " Calibration " section of this manual.

WARNING

- **Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.**
- **Every time you perform a control solution test, you must enter into the " CTL " test mode so that the test result will not be stored in the meter memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.**

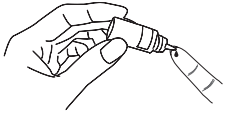
STEP 2. Press the M button

While the " " symbol appears on the display, press the M button and then "CTL" will appear on the display. With the "CTL" sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, press the M button again, and the "CTL" sign will disappear.



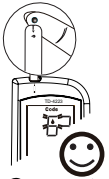
STEP 3. Obtain Control Solution

Shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and place the drop on your fingertip first.



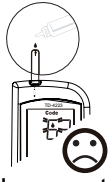
STEP 4. Apply Control Solution

Move your finger (with control solution on it) to meet the absorbent hole of the test strip and the drop will be automatically drawn into the test strip. Remove your finger until the confirmation window is filled. The meter begins to count down.



Correct

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface or on your finger tip first. Then touch the test strip to the drop.



Incorrect

STEP 5. Read and Compare the Result

After counting to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range.

Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of “Problem in Operation” in troubleshooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly.

TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

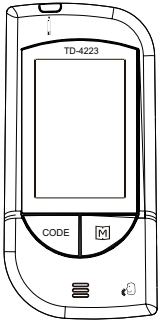
A. Blood Glucose Meter

B. Test Strip

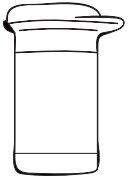
C.Lancing Device

D.Sterile Lancet

A

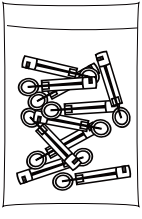


B



C

D



WARNING

To reduce the chance of infection:

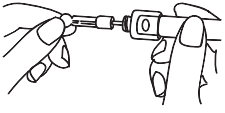
- Never share a lancet or the lancet device with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancet device.

■ Testing Procedure

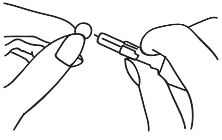
Wash and dry your hands first before starting.

STEP 1. Set the Lancing Device

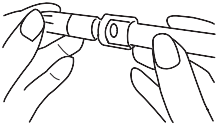
Screw off the cap of Lancing Device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



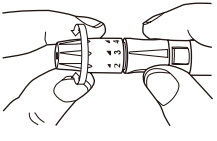
Twist the protective disk until it separates from the lancet.



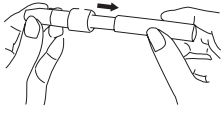
Replace the lancet device cap. Turn the cap until it is snug but not too tight.



The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip in either direction until the number lines up with the Arrow:
1-2 for soft or thin skin
3 for average skin
4-5 for thick or calloused skin

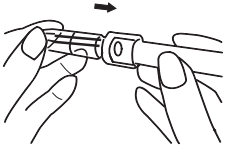


Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.



▶ Blood from sites other than the fingertip

A clear cap makes it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, replace the lancet device cap with the clear cap. Turn the clear cap until it is snug but not too tight, and then slide the ejection/ cocking control back until it clicks.



Note: The clear cap is an optional accessory, please contact your local customer service

The lancing device is now ready. Set aside for later use.

STEP 2. Insert Test Strip

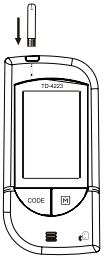
Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the following in sequence:

→ “CH” and “ ”

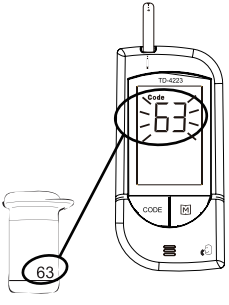
→ ambient temperature

→ flashing code number

→ date, time, flashing “ ” and the code number



Make sure the code number showed on the screen is the same as the code number printed in the test strip vial. If the code numbers are different, please refer to the section of “**Calibration** ”, for the procedure of coding.



STEP 3. Get a Drop of Blood

Select the puncture site either in finger or in other parts (AST). Clean the puncture site with 70% alcohol cotton and let it air-dry.

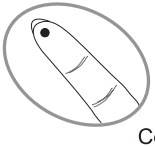
▸ **Fingertip**

Hold the Lancing Device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete.

▸ **Sites other than fingertip**

Please refer to the section of “About AST” for available punctured sites. After penetration, discard the first drop of blood with a clean tissue paper or cotton. Then gently squeeze the punctured area to obtain blood. But be careful **NOT to smear the blood sample.**

The volume of blood sample must be at least 0.7 microliter (◦ actual size).



O
Correct

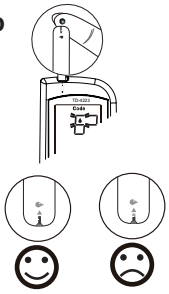
X
Incorrect

PLEASE NOTE

- Choose a different spot each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- Before you decide to do AST, please consult your health professional first.
- Since the first drop of blood usually contains tissue fluid and serum, which may affect the test result, it is recommended to be discarded.

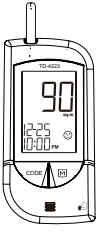
STEP 4. Apply Blood into the Test Strip

When " ▲ " is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is **fully covered** with blood. The meter then begins to count down automatically.



STEP 5. Obtain an Accurate Result in 7 Seconds

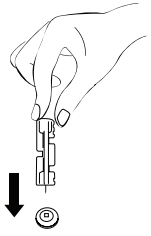
The result of your blood glucose test is shown after the meter counts to 0. This reading is automatically stored in the meter.



PLEASE NOTE

- Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to restart the test procedure.
- The blood should completely fill the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting, **NEVER** try to add more blood to the test strip. **Discard the test strip and retest with a new one.**
- If you have trouble filling the test strip, please contact the customer service for help.

STEP 6. Remove the Lancet



Always use caution when removing the lancet.

Take the lancet out carefully. Place the disk on a hard surface and push the exposed tip into the protective disk.

WARNING

The used lancet and the used test strip may be potentially biohazard. Please discard it carefully according to your local regulations.

■ Expected Test Results

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that **keeping blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60% *[3]
The results you get with the Advocate™ TD-4223A/B. system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

[3]

Time of day	Glucose range for people without diabetes(mg/dL) / (mmol/L)	Your target range (mg/dL)/(mmol/L)
Before breakfast	(70~05)/ (3.9~5.8)	------(mg/dL)/(mmol/L)
Before lunch or dinner	(70~ 110)/ (3.9~6.1)	------(mg/dL)/(mmol/L)
hour after meal s	Less than(160)/(8.9)	------(mg/dL)/(mmol/L)
hour after meal s	Less than(120)/(6.7)	------(mg/dL)/(mmol/L)
Between 2 and 4 AM	Greater than (70)/(3.9)	------(mg/dL)/(mmol/L)

Source: Krall,L.P., and Beaser, R.S :Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989),138

* [3]: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

COMPARING METER AND LABORATORY RESULTS

Test results from the meter and laboratory are both expressed in plasma-equivalent units. However, the result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on limitations.) To make an accurate comparison between meter and laboratory results, follow the guide-lines below.

Before you go to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- It is best to fast for at least eight hours before doing comparison tests.
- Take your meter with you to the lab.

While at the lab:

Make sure that the samples for both tests (the meter test and the lab test are taken and tested within 5 minutes of each other).

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress*[1]. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL(3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test*[2].

Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

*[1]: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (988), April, 49-5 .

*[2]: Sacks, D.B.:"Carbohydrates. "Burtis, C.A.,and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (994), 959.

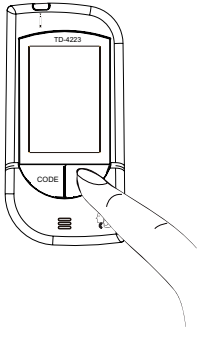
USING THE METER MEMORY

View Results on the Meter

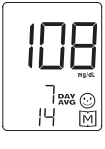
Your meter stores the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14, 21, 28, 60 and 90-day averages of your blood glucose test results. You can review the test results in memory with these easy steps.

STEP 1. Enter the Memory Mode

With the meter turned off, press the M button twice. The 7-day average will appear, indicating that you are in the memory mode. If you continue to press the M button, the 14, 21, 28, 60 and 90day average will appear in order. You can then review the last 450 tests in the memory.



When using the meter for the first time, "---" appears, showing that there are no test results in memory. The 7- day average is calculated from the blood glucose results obtained during the last 7 days.



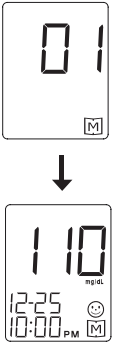
It also indicates how many blood glucose tests have been performed within this period, e.g., 14 (14 tests in the last 7 days).

The 14 day average is calculated from the blood glucose results obtained during the last 14 days. It also indicates how many blood glucose tests have been performed, e.g., 28 (28 tests in the last 14 days).

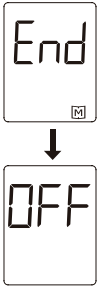
It is all the same to the 21, 28, 60, and 90- day average.

STEP 2. Recall Test Results

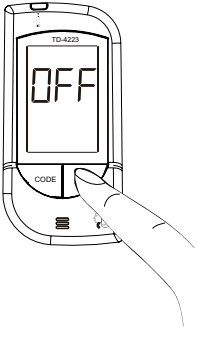
After the 90 day average, the most recent test result with date and time will be shown. Press the M button once and the next most recent test result will appear. Each time you press and release the M button, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest result is dropped as the newest is added.



When reaching the last set of result, “End” and “ Ⓜ “ will be shown on LCD display, and the meter will be turned off automatically.



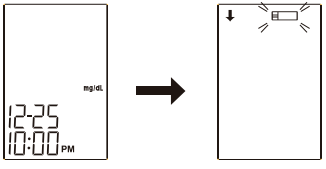
STEP 3. Exit the Memory Mode
Keep pressing the Ⓜ button for 5 seconds to turn off the meter.



PLEASE NOTE

- The control solution results are **NOT** stored in the memory (please also go to page 26 **WARNING** for information). The list of past results and the result average are for blood glucose results only.

- When pressing the M button to recall the test results, the meter will display date, time and the unit of measurement frst. If you do not press the M button within 1minute, the blinking " ▭ " and " ⬇ " will appear. In the meantime, you can choose to insert a test strip to **start testing your blood** or press the M button again to review **the stored test results** .



- If no button is pressed for 3 minutes, the meter will show "OFF" and turn off automatically.

■ Viewing Results on a Personal Computer

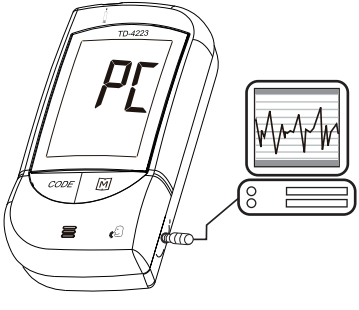
Results in memory can be transmitted to the personal Interface Cable are required before installation. The software can be downloaded from www.dsosi.com. The interface cable is an optional accessory. To learn more about Health Care System Software or to obtain an Interface Cable separately, please contact customer service.

STEP 1. Install Software

Install Health Care System Software on your computer by following the instructions provided on Advocate™'s website: www.dsosi.com.

STEP 2. Connect to Personal Computer

Connect the interface cable to a serial port of your computer. With the meter turned off, connect the Interface Cable to the Data Port of the meter. "PC" will appear on the display, indicating that the meter is ready to transmit data.



STEP 3. Transmit Data

Follow the instructions provided in the software to transmit data. Results transmitted will include date and time. Remove the cable and the meter will automatically turn off.

PLEASE NOTE

While the monitor is connected to the PC, it is unable to perform a blood glucose test.

CARING FOR YOUR METER AND TEST STRIPS

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

■ Cleaning

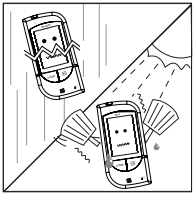
Your meter does not require special maintenance. As no blood or control solution comes in contact with the meter, there is no special cleaning required.

1. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the meter.

■ Storage

Meter Storage

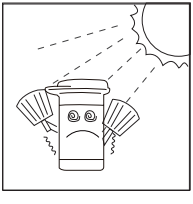
- Storage condition: -20℃~60℃, below 95% relative humidity.
- Always store or transport the meter in its original storage case.



2 Strip Storage

- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

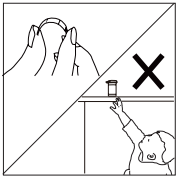
- Storage condition: 4°C-40°C, (39°F- 104°F), below 85% relative humidity. Do not refrigerate.
- Store your test strips in their original vial only. Do not transfer to other container.



- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Touch the test strip with clean and dry hands.

▶ Use each test strip immediately after removing it from the vial.

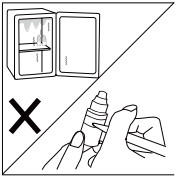
▶ Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.



▶ Do not bend, cut, or alter a test strip in any way.

▶ Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

3. Control solution storage



▶ Storage condition: Store the control solution tightly closed at temperatures below 30°C (86°F). Do NOT refrigerate.

▶ Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.

PROBLEM-SOLVING GUIDE

Following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message or a symbol. In the event of a problem, refer to the information under action.

Never try to disassemble the meter in any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem keeps unsolved, please call the customer service for support.

■ Result Indicator

Special symbols and messages appear together with your test result.

Message	What it means
	☺ appears when your result is at reference range from 70 to 119 mg/dL(3.9 and 6.6 mmol/L)
	low ☹ appears when your result is between 20 to 69 mg/dL(1.1 and 3.8 mmol/L). It indicates that the result is below reference range.
	Lo appears when your result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L)
Lo or low ☹ symbol indicates hypoglycemia (low blood glucose). You should immediately treat hypoglycemia as recommended by your healthcare professional.	
	high ☹ appears when your result is equal to or greater than 120mg/dL(6.6 mmol/L). It indicates that the result is higher than reference range.
	KETONE? appears together with high ☹ when your result is equal or higher than 240 mg/dL(13.3 mmol/L). This indicates there is a possibility of ketone accumulation if you are Type 1 diabetes. Please seek immediate medical assistance.
	Hi appears when your result is above measurement limit, which is higher than 600 mg/dL (33.3 mmol/L).

■ Error Message

Message	What it means	Action
	Appear when the batteries can not provide enough power for a test .	Replace the batteries Immediately.
	Appear when inserting a used test strip .	Test with a new test strip .
	Appear when environmental temperature is below system operation range.	System operation range is 10~40°C (50~104°F).Repeat the test after the meter and test strip have reached the above temperature.
	Appear when environmental temperature is above system operation range.	
	Remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip .
	Problem with the meter.	Review the instructions and re-test with a new test strip. If the above steps do not work, please contact the dealer.

■ Problem in Operation

1. If the meter does not display a message after inserting a test strip:

PROBABLE CAUSE	WH AT TO DO
Battery exhausted.	Replace the battery .
Battery incorrectly installed or absent .	Check that the battery is cor - rectly installed.
Test strip inserted upside-down or incompletely.	Insert the test strip correctly with the contact bars end first and " 💧" facing up.
Defective meter.	Please call the dealer for service.

2. If the test does not start after applying the sample:

PROBABLE CAUSE	WH AT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip .
Sample applied after automatic shutoff (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing " 💧" appears on the display.
Defective meter .	Please call the dealer for service.

3. If the control solution test result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instruction thoroughly and repeat the test again.
Improper code number.	Check if the code number on the display matches the code number on the test strip vial.
Do not shake the control solution vial very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiration date or the discard date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Meter malfunction.	Contact local customer service.

SPECIFICATIONS

Model No.:TD-4223 A/B
Dimension&Weight: 96mm(L) x 20mm(W) x 45mm(H) / 68g
Power source: two 1.5V AAA alkaline batteries
Battery life: Over 1,000 determinants
Display: Large LCD
Memory: 450 measurement results with date and time
Auto electrode inserting detection
Auto sample loading detection
Auto reaction time count-down
Sleeping mode: Power consumption less than 80uA
Auto turn-off after 3 minutes without action
Temperature warning
Operating condition: 10°C~40C, (50°F~104°F)
below 85% R.H.
(noncondensing)
Storage/Transportation condition: 4°C~40°C, (39°F~104°F)
below 85% R.H.
Measurement Units: Either mg/dL or mmol/L
Measurement Range: 20~600mg/dL (1.3~33.3mmol/L)

The device has been certifed to meet the electrical and safety requirements of: IEC 60601-1, EN 60601-1, IEC 61010-1, EN 61010-1, EN 61010-2-101, EN 60601-1-2, EN 61326.

SYMBOL INFORMATION

Symbol	Referent
	In vitro diagnostic medical device
	Do not re-use
	Consult operating instruction
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
	Manufacture
SN	Serial Number
	Caution, consult accompanying documents
	Biological risks

Advocate Warranty Registration Information

Customer Care
Call us with Questions or Comments about your Advocate Blood Glucose Monitor. We are here to help. 9am - 5pm EST., Mon - Fri.

Toll Free -866-373-2824 www.dsosi.com

Important
Before using these products carefully read the owner's manual. For in vitro diagnostic use only. Store at room temperature below 86˚F (30˚C). Keep out of direct sunlight and humidity.

Warranty
The Advocate Glucose Monitor is warranted to be free of defects in material and workmanship for the period of one (1) year from the date of purchase. The warranty is not transferable. This warranty does not apply to the performance of an Advocate Meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way.

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